

Invention to function as bulking agents in edible formulations. Each piece of art concerns a single species of gum, and does not suggest Applicants' unified definition of molecular weight, viscosity and proven functional performance in foods as sucrose replacers and bulking agents. Tomita neither discloses, nor suggests, a generic class of bulking agents derived from food gums.

Section 1.131 Affidavits

The first Affidavit establishes that Applicants had prepared three species of the bulking agents from guar gum, locust bean gum and tamarind seed gum, each characterized by the viscosity and polymer size limits of the claims, and successfully used the bulking agents in foods prior to the filing date of the Tomita reference. Guar gum and locust bean gum are galactomannan gums, species related to konjac gum, a glucomannan gum. Thus the first Affidavit establishes the anticipatory reduction to practice of three species of a genus (i.e., three species of depolymerized food gums selected from a generic group of seven species of gums, each having a DP of 3 to 75 and a maximum viscosity with demonstrated, useful functional performance in foods). The claimed genus is thereby documented (and the Tomita bulking agent is suggested) by the first Affidavit. Assuming the Tomita patent is a Section 103 reference, then the first affidavit is adequate to antedate the reference.

The second 1.131 Affidavit includes an Invention Disclosure Statement document which expressly discloses the generic concept of "the use of the soluble heteropolysaccharide sources (e.g., guar, locust bean gum and tamarind gum) as the base material for the preparation of our bulking agent". The named species (guar, etc.) are expressly identified as examples of the genus, not limitations on the genus. The second Affidavit further discloses the concept of using the genus comprising water soluble hydrolysates of food gums, reciting "the invention described here overcomes the difficulties in utilizing gums as bulking agents. Enzymes are used to depolymerize the gums. With the shorter polymers and lower viscosities, the gums can be used at useful sucrose replacement levels, such as 15% of the weight (50% replacement of sucrose) of a typical yellow cake. The advantage of these products over current bulking agents is the balance between functionality and digestibility. No other bulking agent produced from natural heteropolysaccharides provides both of these benefits." Thus the genus was defined as "bulking agents" having the advantage over the art of a "balance between functionality and digestibility." The bulking agents are produced from "gums" which are "soluble" "natural heteropolysaccharides".

Notwithstanding the Examiner's comments, the second Affidavit expressly establishes that Applicants were in possession of a generic invention with language clearly indicating that the species named in the Invention Disclosure Statement document are "examples" of the invention. The essential scope of the generic invention is described in the document in functional and structural terms, and the claims are limited to a specific group of gums which define the invention over the art.

If, as the Examiner states and Applicants dispute, Tomita is a Section 102(e) reference, then the

species disclosed in the Tomita reference (i.e., bulking agent having no viscosity limits which is a hydrolysate of konjac gum) must anticipate the genus claimed in Applicants' claims (i.e., hydrolysates of food gums selected from the group consisting of guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan and alginates, all having defined molecular weights and viscosity characteristics). It follows that the second Affidavit documenting invention of the claimed chemical genus must antedate the Tomita reference. A Section 102 reference and a claim properly rejected on it must read on each other with respect to each element and limitation. Thus, if the Tomita reference is a Section 102 reference, then Applicants' second 1.131 Affidavit antedates the Tomita reference and removes it as prior art herein.

As for the Examiner's comment that the Section 1.131 Affidavit is inadequate because it does not disclose all members of the Markush group, specifically the konjac gum taught by the Tomita reference, both the Examiner's comment and the relevant language of M.P.E.P. Section 715.03 are contrary to the law of the Court of Appeals for the Federal Circuit. See, e.g., In re Schaub et al., 190 USPQ 324 (CCPA 1976); In re Stryker, 168 USPQ 372 (CCPA 1971); In re Clarke, 148 USPQ 665 (CCPA 1966); In re Hostettler, 148 USPQ 512 (CCPA 1966); and In re Stempel, 113 USPQ 77 (CCPA 1957). The sufficiency of the affidavit must be reviewed on the facts of each case. There is no single rule for a Markush group. Even if a Section 1.131 showing does not make out a *prima facie* case of invention of the entire chemical genus, so long as it (a) shows completion of the invention of a species disclosed in the reference, or (b) shows completion of the invention of a species rendering obvious the species disclosed in the reference, or (c) shows completion of a sufficient number and type of species to establish a generic invention encompassing the species disclosed but not claimed in the invention, then priority is established and the reference is removed. See In re Stempel, 113 USPQ 77 (CCPA 1957) and Ex parte Clark, 60 USPQ 72 (Bd. App., 1943), cited therein.

In Applicants' case, the konjac gum of the reference is a heteropolysaccharide comprising two monosaccharides (glucose and mannose). Thus it may be classified as a homolog or a very closely related species to the guar gum and locust bean gum of the first Affidavit which are heteropolysaccharides comprising two monosaccharides (galactose and mannose). Other, more distant species within Applicants' claimed genus include heteropolysaccharides comprising both monosaccharides and the acids of monosaccharides, together with other species of heteropolysaccharides which comprise substituted and unsubstituted sugar acids, and heteropolysaccharides which comprise three monosaccharides (e.g., tamarind seed gum which comprises glucose, xylose and galactose). The first 1.131 Affidavit establishes a reduction to practice of three species of food gums within the claimed genus of seven species of gums at a date prior to the effective date of the reference. The second Affidavit establishes the generic concept of the claimed invention and discloses three species of the generic invention. Thus, the 1.131 Affidavits submitted herein establish a generic invention which either (a) anticipates or (b) makes obvious the species disclosed in the Tomita reference. See, In re Shokal, Devlin and Winkler, 113 USPQ 283 (CCPA, 1957) at 285 ("...it seems evident therefrom that such number will vary depending upon the circumstances of

particular cases. Thus, in the case of a small genus such as the halogens consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundred of species, a considerably larger number of reductions to practice would probably be necessary"), which describes the number of species needed in an affidavit to establish reduction to practice of a generic invention. See also, In re Schaub, et al., 190 USPQ 324, at 326 (CCPA, 1976), and In re Clarke, 148 USPQ 665, at 668-669 (CCPA 1966) which define closely related species within a genus having common properties for Section 1.131 affidavit purposes.

Rejection under Section 103 over Hill and Barnett

In response to the Examiner's alternate rejection over Hill in view of Barnett under Section 103, Applicants note the Examiner's statement that the references must be addressed in combination.

The Court of Appeals for the Federal Circuit has held that something in the prior art as a whole must suggest the desirability and, therefore, the obviousness of combining particular pieces of art. See, e.g., Uniroyal v. Rudkin-Wiley, 5 USPQ 2d 1434 (CAFC 1988). In the case of the Hill and Barnett references there is no suggestion to combine a particular viscosity characteristic, or to combine a particular degree of polymerization, or to combine a particular molecular weight range of the hemicellulosic materials of Barnett with a non-cellulosic heteropolysaccharide such as guar gum, for use as a bulking agent in food products.

Neither the Hill nor the Barnett reference contains a suggestion that the optional depolymerization treatment level of Barnett would be useful to treat the guar gum used by Hill. In fact, Barnett's implied teaching is that the degree of conversion (depolymerization) of hemicellulose is NOT critical to the use of Barnett's claimed group (the claimed group contains materials which are highly converted or not converted at all) of hemicellulose materials useful as food bulking agents. See Claim 1 of Barnett. The teachings of Barnett would not lead one to further convert Hill's guar gum so that it may be used as a bulking agent in food. Instead, the Barnett teachings would suggest that depolymerization, molecular weight and the resultant viscosity changes are not critical to the use of bulking agent in foods. Of course, Barnett is silent on the topic of depolymerized guar gum and, therefore, suggests nothing which would cause one to combine its teachings with those of Hill.

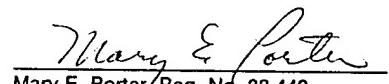
In fact, as shown in data produced by Applicants on page 25, lines 15-32, the degree of depolymerization and the resultant viscosity characteristics of the bulking agent are critical to the efficacy of Applicants' bulking agent when used in foods as a functional substitute for sucrose and other caloric ingredients.

Finally, Applicants repeat and reallege the relevant remarks submitted with prior amendments in the above-captioned patent application. For the reasons of record and the reasons set forth above, Applicants believe the cited references fail to state a prima facie case of obviousness.

CONCLUSION

In view of the affidavits, amendments and remarks submitted herein, Applicants respectfully request allowance of Claims 29-35.

Respectfully submitted,



Mary E. Porter Reg. No. 33,440
Attorney for Applicants
Tel. 908-685-5127

National Starch and Chemical Company
P.O. Box 6500
Bridgewater, New Jersey 08807

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